REMARKS/ARGUMENTS

Claims 1-6 have been rejected. Claims 1-6 have been cancelled without prejudice to or disclaimer of the subject matter encompassed thereby in order to further prosecution of this application. Applicants expressly reserve the right to file continuing applications or take other such appropriate measures to seek protection for the inventions encompassed by the cancelled subject matter.

Claims 7-10 have been added directed to methods of use of ampicillin or clarithromycin in the preparation of a remedy for treating pulmonary sarcoidosis. Support for these claim amendments may be found throughout the specification, as described more fully below.

The expression "agent for treating pulmonary sarcoidosis" in the new claim 7 is supported by the description in the specification. The application describes that indigenous *P. acnes* plays an extremely important role in pulmonary granuloma formation by extrapulmonary *P. acnes* sensitization, but is also clinically useful for sterilizing treatments with antibacterial substances as a pulmonary sarcoidosis treatment (specification page 19, last 4 lines to page 20, line 2). See also Example 2 wherein experimental models by extrapulmonary *P. acnes* sensitization are used as a model animal of sarcoidosis, and experiments administering antibiotics are performed to the model (*e.g.*, the description concerning Fig. 4A to 4K). Further, in the above new claim 7, the antibiotics are specified to ampicillin and clarithromycin, as described in Fig. 7, etc.

The expression "for decreasing pulmonary granulomatous" in the above new claim 8, is substantially supported by the description of the specification. Decrease of *P. acnes* by treatment with antibacterial substances decreased pulmonary granulomatous lesions, whereas intrapulmonary preadministration of *P. acnes* aggravated pulmonary granulomatous lesions (Figs. 6A, B) (specification page 19, last 8 lines to last 4 lines).

The above new claims 9 and 10 specify the antibiotics to be used, as described in Fig. 7, etc.

For the reasons described above, no new matter has been introduced by way of these claim amendments.

Claims 7-10 are currently pending in the application. Reexamination and reconsideration of the claims are respectfully requested in view of the following remarks. The Examiner's

comments in the Office Action dated August 22, 2008 are addressed below in the order set forth therein.

The Objection to the Specification Should Be Withdrawn

The Examiner has objected to the specification on the basis that there is no reference to its priority claim. The specification has been amended to include a cross-reference paragraph, as described above. Accordingly, this objection has been obviated and Applicants request that it be withdrawn.

The Rejections Under 35 U.S.C. §102(b) Should Be Withdrawn

Claims 1-3 are rejected under 35 USC 102(b) as being anticipated by Baroody *et al.* (U.S. Patent No. 5,733,886). This rejection is traversed with respect to the remaining claims for the reasons provided below.

Applicants have cancelled claims 1-3 and presented new claims directed to methods of use in the preparation of a remedy for treating pulmonary sarcoidosis. Although Baroody *et al.* disclose a composition suitable for treating acne comprising clindamycin and benzoyl peroxide, Baroody *et al.* do not describe the use of clindamycin to treat pulmonary sarcoidosis and therefore do not describe each and every element of the current claims. Accordingly, Applicants submit that Baroody *et al.* do not anticipate the current claims and request that this rejection be withdrawn.

The Rejections Under 35 U.S.C. §103(a) Should Be Withdrawn

Claims 1-6 are rejected under 35 U.S.C. §103(a) as being obvious in view of the combination of Eishi *et al.* (2002) *J. Clin. Microbiol.* 40:198-204 with Baroody *et al.* Claims 1-6 have been cancelled, as described above. This rejection is traversed with respect to the newly presented claims for the reasons provided below.

The U.S. Supreme Court recently held that the "teaching, suggestion, motivation to combine" (TSM) test promulgated by the Federal Circuit provides a "helpful insight" when assessing obviousness. *KSR Int'l Co. v. Teleflex, Inc.*, No. 04-1350, slip op. at 14 (U.S. Apr. 30, 2007). The Court further stated that "a patent composed of several elements is not proved

obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.* Furthermore, any rejection for obviousness requires a reasonable expectation of success. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991).

Baroody et al. describe that a composition comprising clindamycin and benzoyl peroxide is suitable for the treatment of acne induced by *P. acnes*. However, Baroody *et al.* do not teach that ampicillin or clarithromycin can be used for the treatment of pulmonary sarcoidosis.

Eishi *et al.* describe that samples from biopsies of lymph nodes from pulmonary sarcoidosis patients contained greater amounts of genetic material from propionibacterium than mycobacterium (see, for example, Abstract). However, Eishi *et al.* do not provide definitive evidence that microbial infection is the cause of pulmonary sarcoidosis. As described in the introductory paragraphs of Eishi *et al.*, microbial infection is merely one of multiple theories concerning the causes of sarcoidosis. In addition, even if microbial infection is the cause for sarcoidosis, there are a large number of candidate microorganisms that could be associated with sarcoidosis, such as tuberculosis bacteria, atypical mycobacterial, cell wall deficient acid fast bacillus, Microplasma pneumoniae, Nocardia, propionibacterium, Epstein-Barr virus, adenovirus, Herpes Simplex virus, and others. Further, it is possible that microbial infection in combination with other causes may be essential for the onset/development of sarcoidosis. Accordingly, Eishi *et al.* merely describe within their samples the relative levels of genetic material from two of many microbial sources, and does not provide evidence that would lead one of skill in the art to reasonably conclude that pulmonary sarcoidosis is caused by propionibacterium infection.

From the above discussion, one of skill in the art would not have had a reason to combine Baroody *et al.* and Eishi *et al.* to arrive at the treatment methods of the current claims. Furthermore, even if one of skill in the art had combined Baroody *et al.* and Eishi *et al.*, they not have had a reasonable expectation of success in the use of ampicillin or clarithromycin for the treatment of pulmonary sarcoidosis (as described, *e.g.*, in Fig. 7 of the present invention). Accordingly, Applicants submit that the present claims are nonobvious in view of the cited references and request that this rejection be withdrawn.

CONCLUSION

In view of the aforementioned amendments and remarks, Applicants respectfully submit that the objection to the specification and rejections of the claims under 35 U.S.C. §§102(b) and 103(a) are overcome. Accordingly, Applicants submit that this application is now in condition for allowance. Early notice to this effect is solicited.

It is not believed that extensions of time or fees for net addition of claims are required. However, in the event that extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 C.F.R. §1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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